

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
8 July 2004 (08.07.2004)

PCT

(10) International Publication Number
WO 2004/057341 A3

- (51) International Patent Classification⁷: **G01N 33/68**, 33/82
- (21) International Application Number:
PCT/GB2003/005607
- (22) International Filing Date:
22 December 2003 (22.12.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
0229747.1 20 December 2002 (20.12.2002) GB
- (71) Applicant (for all designated States except US):
AXIS-SHIELD ASA [NO/NO]; Ulvenveien 87, N-0510 Oslo (NO).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): SUNDREHAGEN, Erling [NO/NO]; Axis-Shield ASA, Ulvenveien 87, N-0510 Oslo (NO).
- (74) Agent: FRANK. B. DEHN & CO; 179 Queen Victoria Street, London EC4V 4EL (GB).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report:
21 October 2004
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CVD ASSAY

(57) Abstract: An assay method for the detection of potential for CVD or propensity to CVD in a human or non-human animal subject, said method comprising assessing the concentration of calprotectin in a calprotectin-containing sample taken from said subject.

WO 2004/057341 A3

INTERNATIONAL SEARCH REPORT

National Application No

PCT/GB 03/05607

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01N33/68 G01N33/82

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	LAGASSE E ET AL: "MOUSE MRP8 AND MRP14, TWO INTRACELLULAR CALCIUM-BINDING PROTEINS ASSOCIATED WITH THE DEVELOPMENT OF THE MYELOID LINEAGE" BLOOD, W.B. SAUNDERS, PHILADELPHIA, VA, US, vol. 79, 1992, pages 1907-1915, XP000653772 ISSN: 0006-4971 page 1908	1-9
A	WO 00/11479 A (COCKBAIN JULIAN ;AXIS BIOCHEMICALS ASA (NO); SUNDREHAGEN ERLING (N) 2 March 2000 (2000-03-02) abstract; claims	1-9

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

13 August 2004

Date of mailing of the international search report

26.08.04

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

GONCALVES M L F C

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 03/05607

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 455 160 A (FAGERHOL MAGNE K ET AL) 3 October 1995 (1995-10-03) column 2 - column 4	1-9
A	US 4 833 074 A (FAGERHOL MAGNE K ET AL) 23 May 1989 (1989-05-23) cited in the application abstract; claims	1-9
A	PECHKOVSKY D V ET AL: "Calprotectin (MRP8/14 protein complex) release during mycobacterial infection in vitro and in vivo." FEMS IMMUNOLOGY AND MEDICAL MICROBIOLOGY. NETHERLANDS SEP 2000, vol. 29, no. 1, September 2000 (2000-09), pages 27-33, XP002279820 ISSN: 0928-8244 page 29	1-9
A	US 5 776 348 A (DRETLEER STEPHEN P ET AL) 7 July 1998 (1998-07-07) column 7, line 26 - line 43	14-27
A	KIDO JUN-ICHI ET AL: "CALPROTECTIN IN GINGIVAL CREVICULAR FLUID CORRELATES WITH CLINICAL AND BIOCHEMICAL MARKERS OF PERIODONTAL DISEASE" JOURNAL OF CLINICAL PERIODONTOLOGY, COPENHAGEN, DK, vol. 26, no. 10, 1999, pages 653-657, XP009030803 page 653 - page 654	26,27
A	SEMB A G ET AL: "CARDIAC SURGERY AND DISTRIBUTION OF THE LEUKOCYTE L1 PROTEIN-CALPROTECTIN" EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY, SPRINGER VERLAG, BERLIN, DE, vol. 5, no. 7, 1991, pages 363-367, XP009030797 ISSN: 1010-7940 page 364	14-27
A	WO 98/20355 A (MATTHEWS DEREK PETER ; NYCOMED PHARMA AS (NO); DALE SIRI (NO); HOLTUND) 14 May 1998 (1998-05-14) examples	14-27
A	US 2002/168784 A1 (BREMNES DAG ET AL) 14 November 2002 (2002-11-14) abstract	25
	-/--	

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 03/05607

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>SAATVEDT K ET AL: "RELEASE OF INTERLEUKIN-8 AND CALPROTECTIN DURING AND AFTER PAEDIATRIC CARDIOPULMONARY BYPASS WITH AND WITHOUT ULTRAFILTRATION" SCANDINAVIAN JOURNAL OF THORACIC AND CARDIOVASCULAR SURGERY, STOCKHOLM, SE, vol. 30, no. 2, 1996, pages 53-59, XP009030799 ISSN: 0036-5580 page 55</p>	14-27
A	<p>MOEN O ET AL: "ROLLER AND CENTRIFUGAL PUMPS COMPARED IN VITRO WITH REGARD TO HAEMOLYSIS, GRANULOCYTE AND COMPLEMENT ACTIVATION" PERFUSION, XX, XX, vol. 9, no. 2, March 1994 (1994-03), pages 109-117, XP009030798 page 109 - page 111</p>	14-27
A	<p>BRUN J G ET AL: "EFFECTS OF HUMAN CALPROTECTIN (L1) ON IN VITRO IMMUNOGLOBULIN SYNTHESIS" SCANDINAVIAN JOURNAL OF IMMUNOLOGY, BLACKWELL SCIENCE PUBL., OXFORD, GB, vol. 40, no. 6, December 1994 (1994-12), pages 675-680, XP009030805 ISSN: 0300-9475 page 675</p>	26,27

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 03/05607

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/ GB 03 /05607

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-10

assay method for the detection of potential or propensity
for cardiovascular disease

2. claims: 14-27

assay method for the determination of calprotectin in a body
fluid by turbidimetry; kit and automated apparatus
therefor; methods of diagnostic using the turbidimetric
assay method.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 03/05607

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0011479	A	02-03-2000	AU 5436499 A EP 1105739 A1 WO 0011479 A1 JP 2002523749 T US 6417006 B1	14-03-2000 13-06-2001 02-03-2000 30-07-2002 09-07-2002
US 5455160	A	03-10-1995	CA 2123856 A1	28-11-1994
US 4833074	A	23-05-1989	BE 900119 A1 CH 661048 A5 DE 3425186 A1 DK 338484 A FR 2550205 A1 GB 2143239 A , B IT 1177889 B JP 2049238 C JP 7084479 B JP 60051113 A JP 2558442 B2 JP 7278194 A NL 8402182 A , B, SE 500219 C2 SE 8403630 A	09-01-1985 30-06-1987 24-01-1985 12-01-1985 08-02-1985 06-02-1985 26-08-1987 25-04-1996 13-09-1995 22-03-1985 27-11-1996 24-10-1995 01-02-1985 09-05-1994 12-01-1985
US 5776348	A	07-07-1998	NONE	
WO 9820355	A	14-05-1998	AU 4790597 A CA 2268926 A1 EP 0937259 A1 WO 9820355 A1 JP 2001503863 T NO 992099 A US 6225072 B1	29-05-1998 14-05-1998 25-08-1999 14-05-1998 21-03-2001 30-04-1999 01-05-2001
US 2002168784	A1	14-11-2002	AU 758339 B2 AU 5056599 A CA 2337415 A1 EP 1099108 A1 WO 0005571 A1 JP 2002521660 T NO 20010382 A	20-03-2003 14-02-2000 03-02-2000 16-05-2001 03-02-2000 16-07-2002 23-01-2001